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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,122	09/11/2003	David J. Ecker	DIBIS-0002US.P3	7830
58057	7590	07/09/2008	EXAMINER	
Casimir Jones, S.C. 440 Science Drive SUITE 203 Madison, WI 53711			BERTAGNA, ANGELA MARIE	
			ART UNIT	PAPER NUMBER
			1637	
			NOTIFICATION DATE	DELIVERY MODE
			07/09/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/660,122

**Applicant(s)**

ECKER ET AL.

**Examiner**

ANGELA BERTAGNA

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-33 and 50-62 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 30-33 and 50-62 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 4/8/08  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

1. Applicant's response filed on April 8, 2008 is acknowledged. Claims 30-33 and 50-62 are currently pending. In the response, Applicant amended claims 30, 52, 53, and 61.

Applicant's amendments and submission of a corrected oath have overcome the previously made objections to the oath and claims 52 & 61. Accordingly, these objections have been withdrawn.

This Office Action contains new grounds of rejection not necessitated by amendment in sections 6-13, and therefore, is made non-final.

### ***Information Disclosure Statement***

2. Applicant's submission of an Information Disclosure Statement on April 8, 2008 is acknowledged. A signed copy is enclosed.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph (New Matter)***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 and 50-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Section 2163.03 of the MPEP states, "An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)."

Section 2163.05 of the MPEP states, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Claims 30-33 and 50-62 are drawn to a method for identifying a virus comprising nucleic acid amplification and mass spectroscopy. The method comprises amplifying viral nucleic acids using primers that hybridize to sequences flanking a variable region, determining the base composition of the resulting amplification products by mass spectroscopy, and comparing the base composition to calculated or measured base compositions of analogous amplification products of one or more known viruses present in a database comprising five or more base compositions.

Claim 30, from which claims 31-33 and 50-62 depend, has been amended to recite that determining the base composition of the amplified products "identifies the number of A residues, C residues, T residues, G residues, U residues, analogs thereof, and/or mass tag residues thereof". The previous version of claim 30 recited that determining the base composition of the amplified products "identifies the number of A residues, C residues, T residues, G residues, U residues, analogs thereof, and mass

tag residues thereof". Thus, the amendment to claim 30 broadens the scope of the claim to encompass obtaining base compositions that identify the number of A residues, C residues, T residues, G residues, U residues, analogs thereof, **or** mass tag residues thereof.

Applicant states that support can be found throughout the specification (see page 4), but does not point to any specific passage(s) in the disclosure providing support for the amendment.

The specification defines the base composition as "the exact base composition determined from a bioagent identifying amplicon (page 25)." Based on this explicit definition, the base composition must identify the number of all nucleotides suspected to be present in a given amplicon (*i.e.* the number of adenines, guanines, cytosines, thymines, uracils, mass tag nucleotides, and nucleotide analogs) and not just a subset of nucleotides. Also, the examples described on pages 23-24 and 40-45 only teach base compositions wherein the complete base composition (*i.e.* the number of adenines, guanines, cytosines, uracils, thymines, nucleotide analogs, **and** mass tag nucleotides) was determined. Since the specification does not teach base compositions wherein the number of only a subset of nucleotides is determined, and the explicit definition on page 25 of the specification requires a determination of all of the nucleotides present in a given amplicon, the broadening amendment to claim 30 introduces new matter. Accordingly, claims 30-33 and 50-62 are rejected under 35 U.S.C. 112, first paragraph.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-33 and 50-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-33 and 50-62 are vague and indefinite, because it is unclear how a base composition can be determined without determining the number of all possible nucleotides present in a given amplicon. As discussed above, page 25 of the specification explicitly defines the base composition as "the exact base composition determined from a bioagent identifying amplicon." Based on this definition, it is unclear how a determination of the number of only a subset of nucleotides present in an amplicon would constitute a base composition, since the number of all of nucleotides present in the amplicon would be unknown.

***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 30-33 and 50-62 are directed to an invention not patentably distinct from claims of 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of commonly assigned US 7,108,974 B2. Specifically, the methods recited in the instant claims 30-33 and 50-62 are an obvious variant of the methods recited in claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of the '974 patent in view of the prior art of Koster and Campbell (see sections 7 and 8 for further description).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 7,108,974 B2, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claims 30, 32, 33, and 50-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of U.S. Patent No. US 7,018,974 B2 in view of Koster et al. (WO 98/20166; cited previously).

The instant claims are drawn to a method for identifying a viral bioagent in a sample. The method comprises amplifying viral nucleic acids present in the sample using primers that flank a variable region of the viral nucleic acids, determining the base composition of the amplified products using mass spectroscopy, and identifying the viral bioagent by comparing the observed base composition to a database of base compositions obtained from viral nucleic acid amplicons.

Claims 2, 10, 15, and 16 of the '974 patent recite a method for identifying a bacterial bioagent in a sample that includes all of the limitations recited in the instant claim 30 with the exception that the claims of the '974 patent are drawn to the detection of bacterial nucleic acids rather than viral nucleic acids.

The limitations of the instant claim 32 are recited in claim 24 of the '974 patent. The limitations of the instant claims 54-56 are recited in claims 13 and 29 of the '974 patent. The limitations of the instant claim 57 are recited in claims 3 and 12 of the '974



patent. The limitations of the instant claim 58 are recited in claims 7 and 18 of the '974 patent. The limitations of the instant claim 59 are recited in claim 22 of the '974 patent. The limitations of the instant claims 60-62 are recited in claims 26-28 of the '974 patent.

As noted above, the claims of the '974 patent are drawn to the detection of bacterial nucleic acids rather than viral nucleic acids.

Koster teaches methods for analyzing amplification products using mass spectroscopy.

Regarding claims 30, 32, 33, and 50-53, Koster teaches analysis of respiratory pathogens such as rhinovirus (see page 74, line 1) and influenza virus (see page 74, line 8), which is also a biological warfare agent. Koster also teaches analysis of an immunodeficiency virus (HIV) and HCV, which is a member of the flaviviridae family (see page 73, line 21 and page 74, line 21). Koster also teaches comparison of base compositions with both modified and unmodified products (see page 66, for example, as well as page 105, Table II and pages 69-70). At page 105, Table II, Koster provides the base composition of three different PCR products determined by MALDI-TOF. Further, Koster specifically discusses using base composition to analyze mutations as discussed on page 70, where Koster notes, "MS can also be used to determined full or partial sequences of larger DNAs; this can be used to detect, locate, and identify new mutations in a given gene region." In particular, Koster expressly teaches the use of MALDI-TOF for diagnosis of bacterial or viral infections (see pages 73-79). Koster exemplifies this analysis in Example 5.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize the viral targets and mass spectrometry method of Koster when practicing the method recited in the claims of the '974 patent. Since Koster taught that base composition analysis of amplification products was useful for identifying bacterial and viral infections (pages 73-79), an ordinary artisan would have been motivated to additionally analyze viral nucleic acids, such as the clinically relevant viral nucleic acid targets identified by Koster (e.g. HCV, HIV, etc), in order to increase the number of useful applications of the method. Thus, the methods recited in the instant claims 30, 32, 33, and 50-62 are an obvious variant of the methods recited in claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of the '974 patent in view of Koster.

8. Claim 31 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of U.S. Patent No. US 7,018,974 B2 in view of Koster et al. (WO 98/20166; cited previously) and further in view of Campbell et al. (Journal of Virological Methods (1996) 57: 175-179; cited previously).

The methods recited in the instant claims 30, 32, 33, and 50-62 are an obvious variant of the methods recited in claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of the '974 patent in view of Koster, as discussed above.

The claims of the '974 patent do not teach performing the method using multiple primer pairs as required by claim 31.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to modify the method recited in the claims of the '974 patent to use multiple primer pairs since Campbell stated, "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1)." Thus, an ordinary artisan, concerned with the problem of missing variants with a mutation in the conserved region of a virus, could resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants. Thus, the method of claim 31 is an obvious variant of the method recited in claims 2, 3, 7, 10, 12, 13, 15, 16, 18, 22, 24, and 26-29 of the '974 patent in view of Koster and further in view of Campbell.

9. Claims 30-33 and 50-62 are directed to an invention not patentably distinct from claims of commonly assigned US 7,226,739 B2. Specifically, the methods recited in the instant claims 30, 33 and 59 are anticipated by the methods recited in claims 5 and 11 of the '739 patent. Also, the methods of the instant claims 31, 32, 50-58, and 60-62 are an obvious variant of the methods recited in claims 5 and 11 of the '739 patent in view of the prior art of Campbell, Vanderhallen, and Koster (see sections 10-13 below).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 7,226,739 B2, discussed above, would form

the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

10. Claims 30, 33, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 11 of U.S. Patent No. US 7,226,739 B2. Although the conflicting claims are not identical, they are not patentably distinct, because claims 5 and 11 of the '739 patent recite a method for detecting a viral bioagent in a sample that comprises all of the limitations of the instant claims 30, 33, and 59. In other words, the method recited in claims 5 and 11 of the '739 patent anticipates the method recited in the instant claims 30, 33, and 59.

11. Claims 31 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 11 of U.S. Patent No.

7,226,739 B2 in view of Campbell et al. (Journal of Virological Methods (1996) 57: 175-179; cited previously).

As discussed above, the instant claims 30, 33, and 59 are an obvious variant of claims 5 and 11 of the '739 patent.

The claims of the '739 patent do not teach performing the method using multiple primer pairs as required by claim 31 or that the amplification step uses PCR as required by claim 57.

Campbell teaches the use of multiple primers in order to detect every variant (see page 178, column 1). Campbell also teaches PCR amplification (see pages 176-177).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to modify the method of the '739 patent to use multiple primer pairs since Campbell stated, "By using both sets of primers it is highly unlikely that any variant will go undetected (see page 178, column 1)." Thus, an ordinary artisan, concerned with the problem of missing variants with a mutation in the conserved region of a virus, could resolve this concern by repeating the assay with additional primer sets as taught by Campbell, who teaches that the use of additional primer sets will result in improved detection of all variants. An ordinary artisan also would have been motivated to use any form of amplification known to be useful for amplifying viral nucleic acids, such as the PCR amplification method taught by Campbell, recognizing its suitability for the intended purpose. As noted in MPEP 2144.07, selection of a known process based

on its suitability for the intended purpose is *prima facie* obvious in the absence of secondary considerations.

12. Claims 32, 50-53, 58, and 60-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 11 of U.S. Patent No. 7,226,739 B2 in view of Koster et al. (WO 98/20166; cited previously).

As discussed above the instant claims 30, 33, and 59 are an obvious variant of claims 5 and 11 of the '739 patent.

The claims of the '739 patent do not teach applying the method to the detection of a biological warfare agent, a respiratory pathogen, hepatitis C virus, or an immunodeficiency virus, as required by claims 32, and 50-53, respectively. The claims of the '739 patent also do not teach that the primers flank a region about 60-100 nucleotides in length, as required by claim 58. Finally, the claims of the '739 patent do not teach incorporating a molecular mass-modifying tag or a nucleotide analog into the amplification product to limit the number of possible base compositions having the mass of the amplification product as required by claims 60-62.

Koster teaches methods for analyzing amplification products using mass spectroscopy. Koster also teaches comparison of base compositions with both modified and unmodified products (see page 66, for example, as well as page 105, Table II and pages 69-70). At page 105, Table II, Koster provides the base composition of three different PCR products determined by MALDI-TOF. Further, Koster specifically discusses using base composition to analyze mutations as discussed on page 70,

where Koster notes, "MS can also be used to determined full or partial sequences of larger DNAs; this can be used to detect, locate, and identify new mutations in a given gene region." In particular, Koster expressly teaches the use of MALDI-TOF for diagnosis of bacterial or viral infections (see pages 73-79). Koster exemplifies this analysis in Example 5.

Regarding claims 32 and 50-53, Koster teaches analysis of respiratory pathogens such as rhinovirus (see page 74, line 1) as well as influenza virus (see page 74, line 8), which is also a biological warfare agent. Koster also teaches analysis of an immunodeficiency virus (HIV) and HCV, which is a member of the flaviviridae family (see page 73, line 21 and page 74, line 21).

Regarding claim 58, Koster teaches that the amplified products are 67 bp in length (page 87), and therefore, teaches primers that flank a region between 60 and 100 nucleotides in length.

Regarding claims 60 and 61, Koster teaches incorporating nucleotide analogs, such as uridine, into the primers (page 40).

Regarding claim 62, Koster teaches incorporating mass tags into the amplification products to limit the number of possible base compositions (see page 66, for example, as well as page 105, Table II and pages 69-70).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize the viral targets and mass spectrometry method of Koster when practicing the method recited in the claims of the '739 patent. Since Koster taught that base composition analysis of amplification products was useful for identifying

bacterial and viral infections (pages 73-79), an ordinary artisan would have been motivated to additionally analyze viral nucleic acids, such as the clinically relevant viral nucleic acid targets identified by Koster (*e.g.* HCV, HIV, *etc*), in order to increase the number of useful applications of the method. Thus, the methods recited in the instant claims 32, 50-53, 58, and 60-62 are an obvious variant of the methods recited in claims 5 and 11 of the '739 patent in view of Koster.

13. Claim 54-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 11 of U.S. Patent No. 7,226,739 B2 in view of Vanderhallen et al. (Journal of Clinical Microbiology (1998) 36(12): 3463-3467; cited previously).

As discussed above the instant claims 30, 33, and 59 are an obvious variant of claims 5 and 11 of the '739 patent.

The '739 patent does not teach that the method amplifies a polymerase gene as required by claims 54-56.

Vanderhallen teaches analysis of a polymerase gene for typing EMCV (abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to use the method of the '739 patent to type the clinically relevant EMCV by amplifying a polymerase gene, since Vanderhallen stated, "The PCR technique has increased the sensitivity of detection of viral nucleic acids in clinical specimens (see page 3465, column 2)." An ordinary artisan, interested in improving sensitivity of EMCV detection, would have been motivated to combine the PCR method



of Vanderhallen with the mass spectrometric analysis recited in the claims of the '739 patent, in order to identify specific subtypes of viruses that are of clinical significance and permit epidemiological tracking of these viruses.

#### ***Terminal Disclaimer***

14. The terminal disclaimer filed on April 8, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7,217,510 and US 7,255,992 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

15. As noted above, Applicant's amendments and submission of a terminal disclaimer have overcome the previously made objections and rejections. Therefore, Applicant's arguments have been considered, but they are moot in view of the new grounds of rejection presented above.

#### ***Conclusion***

16. No claims are currently allowable. The pending claims are free of the art, but they have been rejected for other reasons, specifically, failure to comply with the first and second paragraphs of 35 U.S.C. 112 and nonstatutory obviousness-type double patenting.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner, Art Unit 1637